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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Garvey et al**

Application No: **09/512,829**

Group Art Unit: **1624**

Filed: **February 25, 2000**

Examiner: **R. Raymond**

For: **Nitrosated and Nitrosylated Proton Pump Inhibitors,
Compositions and Methods of Use**

Attorney Docket No: **102258.284**

Assistant Commissioner of Patents
Washington, DC 20231

**Provisional Response to Restriction Requirement and
Request for Reconsideration of Restriction Requirement under 37 CFR § 1.143**

This response is submitted in reply to the Restriction Requirement dated March 14, 2001, for which a response is due on or before April 14, 2001.

I. Request for Reconsideration of Restriction Requirement

Under 37 C.F.R. § 1.143, Applicants respectfully request reconsideration of the restriction requirement dated March 14, 2001, to the extent that the restriction requirement does not comply with the MPEP. For example, MPEP 817 states that the restriction requirement letter should:

- (1) Identify each group by roman numeral.
- (2) List claims in each group. Check accuracy of numbering of the claims; look for same claims in two groups; and look for omitted claims.
- (3) Give short description of total extent of subject matter claimed in each group, pointing out critical claims of different scope and identifying whether the claims are directed to a combination, subcombination, process, apparatus or product.
- (4) Classify each group.

Applicants respectfully submit that the Examiner has not complied with the requirements for restricting an invention as required in the MPEP. The Examiner in his restriction requirement only refers to the compounds recited in claim 1.

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II. Proposed restriction requirement

Applicants respectfully propose the following restriction requirement for consideration:

Group I:	claims 1-34 and 73-75	drawn to the compounds, compositions, methods of use and kits for the nitrosated and/or nitrosylated proton pump inhibitors
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Group II:	claims 35-72 and 76-78	drawn to the compounds, compositions, methods of use and kits for the parent proton pump inhibitor and nitric oxide donor
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III. Provisional Response to Restriction Requirement

Applicants provisionally elect Applicant's proposed Group II, claims 35-72 and 76-78, with traverse.¹

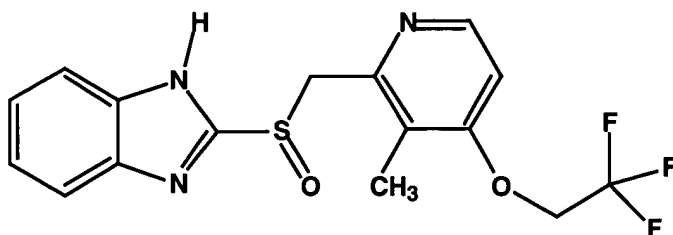
IV. Election of Species

In response to the election of species requirement Applicants provisionally elect, with traverse, lansoprazole as the proton pump inhibitor, and S-nitrosoglutathione as the compound that donates, transfers or releases nitric oxide, induces the production of endogenous nitric oxide or endothelium derived relaxing factor, or is a substrate for nitric oxide synthase.

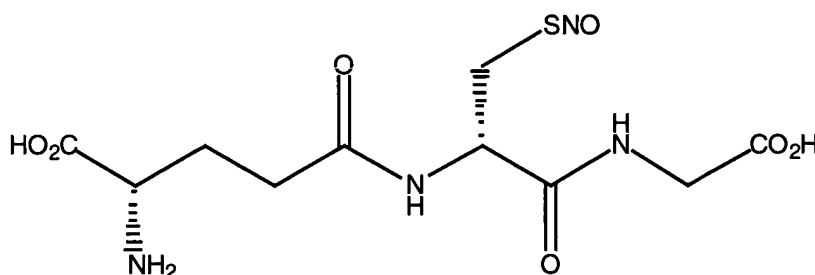
¹ Independent claim 35 recites: "A composition comprising at least one proton pump inhibitor compound or a pharmaceutically acceptable salt thereof, and at least one compound that donates, transfers or releases nitric oxide, or induces the production of endogenous nitric oxide or endothelium derived relaxing factor, or is a substrate for nitric oxide synthase."

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Lansoprazole is represented by the following structure:



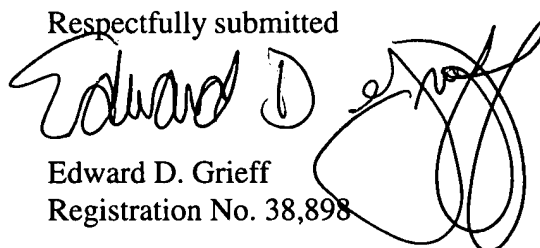
S-nitrosoglutathione is represented by the following structure:



V. Conclusion

Applicants respectfully request that the restriction requirement be withdrawn, and replaced with Applicant's proposed restriction requirement. An early and favorable consideration and allowance of the pending claims is respectfully requested.

Respectfully submitted



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Dated: April 9, 2001

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